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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,455

06/01/2006

Michal Amit

32059

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67801

7590

03/02/2009

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EXAMINER

TON, THAIAN N

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

03/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,455	Applicant(s) AMIT ET AL.	
	Examiner Thaian N. Ton	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-75 and 78-84 is/are pending in the application.
- 4a) Of the above claim(s) 62-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52,55-60,74,75 and 78-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/29/08;8/8/08;6/1/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 52, 53-75, 78-84 are pending; claims 53-54 and 76-77 are cancelled; claims 62-73 are withdrawn; claims 52, 55-60, 74, 75, 78-84 are under current examination.

Election/Restrictions

Claims 61-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/28/08.

Applicant's election of Group I (claims 52, 55-60, 74-74, 78-84) in the reply filed on 11/28/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The Examiner notes that claims 83-84 were inadvertently left out of the restriction requirement, mailed 9/5/08. The claims are found to be part of the elected group and will be examined accordingly.

Applicants further elected SEQ ID NO: 34 for a species election. The Examiner withdraws the species restriction requirement and all species are examined.

Information Disclosure Statement

Applicants' IDS, filed 12/29/08, 8/8/08 and 6/1/06 have been considered.

Claim Objections

Claim 59 is objected to because of the following informalities: the word "isolated" is misspelled in line 1 of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 78 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 78 recites the limitation "said stem cell" in line 1 of the claim. This claim refers to claim 74, which recites generating a human ES cell line (step a) or subjecting cells of the hES stem cell line to differentiating conditions (step b). There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 52, 55, 56, 58-60, 74, 75, 78-80 are rejected under 35 U.S.C. 102(a) as being anticipated by Amit *et al.* (Chapter 7: Subcloning and Alternative Methods for the Derivation and Culture of Human Embryonic Stem Cells from Human Embryonic Stem cells, Ed. A.Y. Chiu and M.S. Rao; January 1, 2003, pp. 127-144).

Amit teach a human ES cell line that was heterozygous for the W128X mutation. They teach that the J-3 cell line has been in continuous culture for over

116 passages and has a karyotype of Normal XY. See p. 132 and Table 2. This mutation is a nonsense mutation (see p. 141, Reference #8).

Amit teach that producing human ES cells lines that harbor different genetic defects, and following the expression of the diseases during differentiation can be used to develop drugs or gene therapy to treat these genetic diseases (p. 132, 1st full ¶). Particularly, Amit teach that human ES cells with W1282X mutation may offer a suitable system for investigation of the nature of cystic fibrosis and help development of drug and gene therapy models for cystic fibrosis (pp. 132-133, bridging ¶).

Accordingly, Amit anticipate the claimed invention.

Claims 52, 55, 56, 58-60 are rejected under 35 U.S.C. 102(a) as being anticipated by Zwaka *et al.* (**Nature Biotechnology**, 21:319-321, March 2003).

Zwaka teach homologous recombination in human ES to successfully target the HPRT1 gene. Zwaka teach that HPRT1 deficiency in humans results in Lesch-Nyhan syndrome (see p. 320, col. 1). Various claimed embodiments that describe properties of the cells (such as maintaining them for 41 passages) are considered inherent properties of the cells. “Products of identical chemical composition can not have mutually exclusive properties.” A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). In the instant case, Zwaka fulfill the limitations of the claims, therefore the properties claimed are inherent in the cells taught by Zwaka.

Accordingly, Zwaka anticipate the claimed invention.

Claims 52, 55, 56, 58-60 are rejected under 35 U.S.C. 102(e) as being anticipated by PGPub US 2006/0128018 A1 (Published June 15, 2006; Filed February 6, 2004).

The '018 document teaches targeted gene delivery by homologous recombination to human ES cells (p. 2, ¶17+). The '018 document teaches the targeting of the HPRT gene, which is located on the X chromosome, and the disruption of this locus, which is found in patients having Lesch-Nyhan syndrome. The '018 document teaches that cells that are deficient in HPRT can be screened and selected for (p. 4, ¶33). The '018 document teaches that ES cells containing a specific genetic modification can be differentiated and used for screening methods (p. 4, ¶35). See above, with regard to the inherent properties of the claimed cells.

Accordingly, the '018 document anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35

U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 74, 75, 78-79, 82-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over PGPub US 2006/0128018 A1 (Published June 15, 2006; Filed February 6, 2004 when taken with PGPUB US 2002/0081668 A1 (published June 27, 2002; filed November 30, 2002).

The '018 document teaches targeted gene delivery by homologous recombination to human ES cells (p. 2, ¶17+). The '018 document teaches the targeting of the HPRT gene, which is located on the X chromosome, and the disruption of this locus, which is found in patients having Lesch-Nyhan syndrome. The '018 document teaches that cells that are deficient in HPRT can be screened and selected for (p. 4, ¶33). The '018 document teaches that ES cells containing a specific genetic modification can be differentiated and used for screening methods (p. 4, ¶35). In particular, the '018 document teaches that after the ES cells are transfected, they are permitted to differentiate by spontaneous aggregation (formation of embryoid bodies) and that the desired differentiated cells can be identified by optical cell sorting techniques, such as FACS. See pp. 3-4, ¶30 and p. 6, ¶53.

The '018 document does not specifically teach utilizing the ES cells in methods of identifying agents suitable for treating a disorder associated with at least one disease-causing mutation. However, prior to the time of the claimed invention, the '668 document teaches utilizing mutated mouse ES cells in the discovery and development of new therapeutic and diagnostic agents (see Abstract). The '668 document teaches assays that can identify compounds that modulate the mutant ES cells, see p. 15, ¶124+, particularly, ¶127. The '668 document teaches that cell-based systems can be used to identify compounds that may act to ameliorate developmental or cell differentiation disorder symptoms (p. 20, ¶162-164, for example).

Accordingly, in view of the combined teachings, it would have been obvious for one of ordinary skill in the art to utilize the mutant human ES cells differentiate these cells, as taught by the '018 document, and then utilize the cells for assays that identify an agent that is suitable for treating a disorder that is associated with the disease-causing mutation, with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to make this modification in view of the '688 document, which provides ample guidance with regard to cell-based assays that can be used to identify putative treatment agents. Additionally, utilizing mutant human ES cells to screen for putative treatment agents would well within the skills of the ordinary skilled artisan.

Thus, the claimed invention, as a whole, is clearly *prima facie* obvious in the absence of evidence to the contrary.

Claim 84 is rejected under 35 U.S.C. 103(a) as being unpatentable over PGPub US 2006/0128018 A1 (Published June 15, 2006; Filed February 6, 2004 when taken with PGPUB US 2002/0081668 A1 (published June 27, 2002; filed November 30, 2002) as applied to claims 74, 75, 78-79, 82-83 above, and further in view of PGPub US 2005/0054092 A1.

The '018 and 668 documents are described above. They do not specifically teach isolating lineage specific cells by mechanical separation of cells tissues and/or tissue-like structures contained within the embryoid body. However, prior to the time of the claimed invention, the '092 document teaches that suspensions of pPS derived cells can be further enriched with desirable characteristics, such as mechanical separation or cell sorting (p. 8, ¶117).

Accordingly, it would have been obvious for one of skill in the art to substitute the method of cell sorting, taught by the '018 document and utilize mechanical separation of differentiated cells within an embryoid body, to isolated cells of interest, with a reasonable expectation of success. In particular, it would

have been obvious to substitute one cell isolation technique for the other to achieve the predictable result of isolating a cell type of interest.

Claims 52, 55, 56, 58-60, 74, 75, 78-80, 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratcliff (**Transgenic Res.**, 1: 177-181, 1992, IDS) when taken with Thomson *et al.* (**Science**, 282: 1145-1147, November 6, 1998) and US Pat. No. 7,390,659 (Issued June 24, 2008) in further view of Elsea *et al.* (**ILAR Journal**, 43(2): 66-79, 2002).

Ratcliff teach the specific disruption of the *cftr* gene at the endogenous locus in mouse ES cells by gene targeting (see Abstract). Ratcliff teach that utilizing these mouse ES cells, transgenic animals can be produced to study pathophysiology and testing of new therapeutic drugs.

Ratcliff do not specifically teach human embryonic stem cells, or methods of using such cells in *in vitro* assays. However, prior to the time of the claimed invention, Thomson teach human embryonic stem cells, and teach that genetic modifications could be produced in ES cells, for reducing or combating immune rejection (p. 1147, 1st col). Thomson teach that human ES cells can be differentiated by allowing the cells to grow to confluence and pile up (production of embryoid bodies, see p. 1146, col. 1, 2nd ¶). Additionally, Thomson teach that human ES cells would be valuable in studies of development and function of tissues that differ between mice and humans, and that screens based upon the *in vitro* differentiation to specific lineages could identify gene targets for new drugs (see p. 1146, col. 2-3, bridging ¶).

Thomson do not specifically teach the *in vitro* assay steps required by the claims. However, prior to the time of filing, the '659 document teaches methods for identifying candidate agents for treating conditions associated with motor neuron degeneration by obtaining embryonic stem cells, wherein the stem cells contain a mutation in a specific gene, contacting the ES cells with retinoic acid to

differentiate the cells into neural progenitor cells, and determining the effect of an agent for use in treatment of a condition associated with motor neuron degeneration. See claim 1.

Accordingly, it would have been obvious to one of ordinary skill in the art, to utilize the technology to produce specific disruptions in mouse ES cells and apply this technology to human ES cells, and then utilize the resultant cells in methods of screening agents suitable for treating a disorder, such as the methods taught by the '659 document, with a reasonable expectation of success. One of ordinary skill in the art would have been sufficiently motivated to make this modification in view of Thomson's teachings who suggest producing genetic modifications in ES cells, and that human ES cells could be used for screening methods *in vitro* and the '659 document provide guidance with regard to the specific steps. Additionally, Elsea provide further guidance to show that various mouse models of human diseases, such as metachromatic leukodystrophy, do not produce a biochemical model that reproduces clinical symptoms (see Abstract) and therefore show a need in the art to produce cells that could be used for screening various human diseases using human cells.

Thus, the claimed invention, as a whole, is clearly *prima facie* obvious in the absence of evidence to the contrary.

Claims 83-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratcliff (**Transgenic Res.**, 1: 177-181, 1992, IDS) when taken with Thomson *et al.* (**Science**, 282: 1145-1147, November 6, 1998) in further view of Elsea *et al.* (**ILAR Journal**, 43(2): 66-79, 2002) as applied to claims 52, 55, 56, 58-60, 74, 75, 78-80, 82 above, and further in view of PGPub US 2005/0054092 A1.

Ratcliff, Thomson, Elsea are described above. They do not specifically teach isolating lineage specific cells by mechanical separation of cells tissues and/or tissue-like structures contained within the embryoid body. However, prior to the

time of the claimed invention, the '092 document teaches that suspensions of pPS derived cells can be further enriched with desirable characteristics, such as mechanical separation or cell sorting (p. 8, ¶117). In particular, the '092 document teaches that FACS sorting can be used (p. 10, ¶144).

Accordingly, it would have been obvious for one of skill in the art to modify the methods taught by Ratcliff, Thomson and Elsea, to include a step of isolating a lineage-specific cell, utilizing either cell sorting, such as FACS sorting, or mechanical isolation techniques, as taught by the '092 document with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to make this modification in order to have a purified population of cells for *in vitro* screening assays.

Claims 57, 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratcliff (**Transgenic Res.**, 1: 177-181, 1992, IDS) when taken with Thomson *et al.* (**Science**, 282: 1145-1147, November 6, 1998) in further view of Elsea *et al.* (**ILAR Journal**, 43(2): 66-79, 2002) as applied to claims 52, 55, 56, 58-60, 74, 75, 78-80, 82 above, and further in view of US Pat. No. 5,972,955.

Ratcliff, Thomson, Elsea are described above. They do not specifically teach a sequence, such as those recited in claims 57 and 81. However, prior to the time of filing, the '995 reference teaches an exact match of SEQ ID NO: 24 (see alignment, below).

Accordingly, it would have been obvious for the ordinary skilled artisan to modify the teachings of Ratcliff, Thomson and Elsea, to produce human ES cells carrying a mutation, such as the W1282X as set forth in SEQ ID NO: 24, associated with cystic fibrosis, with a reasonable expectation of success. One of ordinary skill would have been motivated to make this modification in order to produce ES cells that could then be used for screen therapeutic agents for treatment of cystic fibrosis.

Thus, the claimed invention, as a whole, is clearly *prima facie* obvious in the absence of evidence to the contrary.

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Query Match          100.0%;  Score 6128;  DB 2;  Length 6129;
Best Local Similarity 99.9%;  Pred. No. 0;
Matches 6128;  Conservative 0;  Mismatches 1;  Indels 0;
Gaps 0;

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Qy      1501 GCTGGATCCACTGGAGCAGGCAAGACTTCACTTCTAATGATGATTATGGGAGAACTGGAG 1560
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Qy      1561 CCTTCAGAGGGTAAAAATTAAGCACAGTGGAGAATTTCAATCTGTCTNAGTTTTCTCTGG 1620
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Db      1561 CCTTCAGAGGGTAAAAATTAAGCACAGTGGAGAATTTCAATCTGTCTNAGTTTTCTCTGG 1620

Qy      1621 ATTATGCCTGGCACCATTAAAGAAAAATATCATCTTTGGTGTTTCCTATGATGAATATAGA 1680
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Qy      1741 GACAATATAGTTCTTGGAGAAGGTGGAATCACACTGAGTGGAGGTCAACGAGCAAGAATT 1800
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Art Unit: 1632

Qy 1801 TCTTTAGCAAGAGCAGTATACAAAGATGCTGATTGTATTTATTAGACTCTCCTTTTGGGA 1860
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Qy 1861 TACCTAGATGTTTTAACAGAAAAAGAAATATTTGAAAGCTGTGTCTGTAAACTGATGGCT 1920
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Qy 1921 AACAAAAC TAGGATTTTGGTCACTTCTAAAATGGAACATTTAAAGAAAGCTGACAAAATA 1980
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Db 2701 AAGAGCTTAATTTTTGTGCTAATTTGGTGCTTAGTAATTTTCTGGCAGAGGTGGCTGCT 2760
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Qy 3961 ATAACCTTTGCAACAGTGGAGGAAAGCCTTTGGAGTGATACCACAGAAAGTATTTATTTTT 4020
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Qy 4201 GCTAGATCTGTTTCTCAGTAAGGCCAAGATCTTGCTGCTTGATGAACCCAGTGCTCATTG 4260
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Qy 4321 GTAATTCTCTGTGAACACAGGATAGAAGCAATGCTGGAATGCCAACAATTTTGGTCATA 4380
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Qy      4981  GGGTTATGATTAAGTAATGATAACTGGAAACTTCAGCGGTTTATATAAGCTTGTTATTCCT 5040
Db      4981  |||GGGTTATGATTAAGTAATGATAACTGGAAACTTCAGCGGTTTATATAAGCTTGTTATTCCT 5040
Qy      5041  TTTTCTCTCCTCTCCCATGATGTTTAGAAACACAACCTATATTGTTTGCTAAGCATTCCA 5100
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Qy      5101  ACTATCTCATTTCCAAGCAAGTATTAGAATACCACAGGAACCACAAGACTGCACATCAAA 5160
Db      5101  |||ACTATCTCATTTCCAAGCAAGTATTAGAATACCACAGGAACCACAAGACTGCACATCAAA 5160
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Db      5401  |||AGAGTTTAGCTGGAAAAGTATGTTAGTGCAAATTGTACAGGACAGCCCTTCTTTCCACA 5460
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Db      5461  |||GAAGCTCCAGGTAGAGGGTGTGTAAGTAGATAGGCCATGGGCACTGTGGGTAGACACACA 5520
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Db      5521  |||TGAAGTCCAAGCATTTAGATGTATAGGTTGATGGTGGTATGTTTTTCAGGCTAGATGTATG 5580
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Qy 5821 TATTTTATGAAATATTATGTTAAACTGGGACAGGGGAGAACCTAGGGTGATATTAACC 5880
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Qy 6121 CATTGTGT 6129
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Db 6121 CATTGTGT 6129
|||||

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (571)272-0736. The examiner can normally be reached on 9-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Thaian N. Ton/
Primary Examiner, Art Unit 1632